

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

UNIVERSITY OF MASSACHUSETTS)	
and CARMEL LABORATORIES LLC,)	
)	
Plaintiffs,)	C.A. No. 17-868-CFC-SRF
)	
v.)	PUBLIC VERSION
)	
L'ORÉAL USA, INC.,)	
)	
Defendant.)	

**MOTION NO. 2: L'ORÉAL USA'S OPENING BRIEF IN SUPPORT OF
ITS MOTION FOR SUMMARY JUDGMENT OF INDEFINITENESS
OF THE SKIN ENHANCEMENT CLAIM LIMITATION**

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U.S. Patent No. 6,423,327.....1

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TABLE OF EXHIBITS¹

Exhibit No.	Document
1	U.S. Patent No. 6,423,327, issued to Dobson, Jr. et al. on July 23, 2002
2	U.S. Patent No. 6,645,513, issued to Dobson, Jr. et al. on November 11, 2003
5	Declaration of Gerald B. Kasting, Ph.D., containing true and correct excerpts from the Expert Report of Professor Gerald B. Kasting, Ph.D., dated June 26, 2020
11	Excerpts from the Expert Report of Bozena Michniak-Kohn, Ph.D., dated June 26, 2020
12	Excerpts from the Rebuttal Expert Report of Bozena Michniak-Kohn, Ph.D. Regarding Validity, dated July 21, 2020
17	Excerpts from the deposition transcript of James Dobson, taken May 27, 2020
18	Defendant's Exhibit 1, entered during the deposition of James Dobson, taken May 27, 2020
24	Excerpts from the prosecution history of U.S. Application No. 09/672,348 (later issued as U.S. Patent No. 6,423,327)

¹ “Ex. __” refers to exhibits attached to the Declaration of Nicholas A. Tymoczko in Support of L’Oréal USA, Inc.’s *Daubert* and Summary Judgment Motions, filed concurrently herewith.

I. NATURE AND STAGE OF PROCEEDINGS

Plaintiffs filed this action on June 30, 2017, asserting that L'Oréal USA infringes U.S. Patent Nos. 6,423,327 (“the ’327 patent”) and 6,645,513 (“the ’513 patent”) (together, the “patents-in-suit”). (D.I. 1.)² Both fact discovery and expert discovery have closed. A jury trial is scheduled for February 8, 2021.

II. SUMMARY OF ARGUMENT

1. Each of the patents-in-suit claims a “method for enhancing the condition of unbroken skin of a mammal” comprising “topically applying to the skin a composition comprising a concentration of adenosine in an amount effective to enhance the condition of the skin.” (Ex. 1, 10:17-24; Ex. 2, 10:17-24.)³ This claim language requires that (1) the unbroken skin in fact be “enhanced” *and* (2) the amount of adenosine in the composition actually enhances that skin. (*Id.*)

2. The claim specifies the types of “enhancement[s]” of unbroken skin that must be a result of the amount of adenosine in the composition: “reducing one or more of wrinkling, roughness, dryness or laxity of the skin.” (Ex. 1, 10:19-20.)

The specification states that enhancement occurs when there is a “*noticeable*

² Unless otherwise noted, all emphases have been added and all internal citations, modifications, and quotations have been omitted. The patents-in-suit share a specification and citations are generally provided for the ’327 patent only.

³ This case does not involve the discovery of adenosine, which occurs naturally in the human body and was also known in the cosmetic arts since at least the early 1970s. (Ex. 5, ¶¶ 44-45.)

decrease in the amount of wrinkling, roughness, dryness, laxity, sallowness, or pigmentary mottling of the treated skin.” (*See* Ex. 1, 5:44-48; *see also id.* at 2:35-37.) It further states that a “noticeable decrease” can be assessed *either* by “subjective evaluations by the patient or a second party” *or* non-limiting objective measurements like “skin topography measurements.” (Ex. 1, 5:48-54.) Because these claim terms can be determined through wholly subjective evaluations or multiple, different objective measurements, they fail to inform, with reasonable certainty, those skilled in the art regarding the bounds of the invention and thereby render the claims indefinite.

3. Confronted with an ill-defined claim term characteristic that must result from an unspecified amount of adenosine in the composition, Plaintiffs have shifted positions to now argue that this claim language does not limit the claims at all and should be ignored. For the reasons discussed below, they are indisputably claim limitations, and cannot be ignored.

4. Because indefiniteness is a question of law and there are no genuine issues of material fact concerning the language of the claim, L’Oréal USA respectfully requests that the Court grant summary judgment of indefiniteness.

III. FACTUAL BACKGROUND

The relevant facts are set forth in the Concise Statement of Facts (“SOF”).

IV. LEGAL STANDARDS

A. Summary Judgment

Summary judgment is warranted “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). Questions of law such as indefiniteness may be decided at summary judgment. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015); *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1356 (Fed. Cir. 2005), *abrogated on other grounds by Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014).

B. Indefiniteness

An essential tenet of patent law is that a patent claim must provide clear public notice of its metes and bounds. *See, e.g., Dow Chem. Co. v. Nova Chem. Corp. (Canada)*, 803 F.3d 620, 630 (Fed. Cir. 2015). Accordingly, in 2014, the Supreme Court ruled that a “patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). The interpretation of the patent specification and prosecution history is a matter of law for the Court, as is the ultimate question of indefiniteness. *See Teva Pharms.*,

789 F.3d at 1339, 1341; *HZNP Med. LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 688 (Fed. Cir. 2019).

To satisfy the definiteness requirement, patents must provide “some objective standard . . . to determine the scope of the claimed invention” since the meaning of claim term cannot “depend on the unpredictable vagaries of any one person’s opinion.” *Datamize*, 417 F.3d at 1350-51 (affirming summary judgment). In addition, where there are “multiple methods” of evaluating a claim term that “lead to different results” and a lack of “guidance in the patent or the prosecution history as to which method should be used,” the claim term is indefinite. *See, e.g., Dow Chem.*, 803 F.3d at 634; *ButamaxTM Advanced Biofuels LLC v. Gevo, Inc.*, 117 F. Supp. 3d 632, 641-42 (D. Del. 2015) (granting summary judgment where “multiple legitimate methods exist . . . and such methods of measurement can yield different results”).

V. ARGUMENT

A. The “enhance the condition of the skin” Language Allows for Multiple Conflicting Methods of Measurement

Claim 1 of both patents-in-suit recites “[a] method for enhancing the condition of unbroken skin of a mammal by reducing one or more of wrinkling, roughness, dryness, or laxity of the skin” and further requires the use of adenosine “in an amount effective to enhance the condition of the skin.” (SOF, ¶ 2.)

As can be readily seen, the claims generically refer to “reducing one or more of wrinkling, roughness, dryness, or laxity” without providing reasonable guidance regarding what counts as a “reduction” attributable to the adenosine or how this may be assessed. *See, e.g., Datamize*, 417 F.3d at 1350 (when a “word of degree” is used, the Court must determine whether the patent “specification provides some standard for measuring that degree”). The specification increases the lack of clarity by stating that the enhancement must be a “noticeable decrease,” and that the way to determine if it is “noticeable” or not includes the subjective opinion of a “patient” or a “second party.” (Ex. 1, 5:44-52.) The specification does not provide any examples of enhanced unbroken skin. (Ex. 1, 5:44-9:50.) And it contains no examples of enhanced unbroken skin showing “noticeable” reductions in “one or more of wrinkling, roughness, dryness, or laxity,” let alone such enhancements resulting from a particular amount of adenosine in the composition. (*Id.*)

Plaintiffs’ own expert, Dr. Bozena Michniak-Kohn, has not disputed the subjective nature of the claim term (*see* SOF, ¶¶ 8-9), and Plaintiffs’ Rule 30(b)(6) designee and named inventor on the patents-in-suit, Dr. James Dobson, embraced the subjective nature of the claim at deposition, testifying that subjective methods alone can be used to assess the claim language. (*See, e.g.,* Ex. 17 at 135:4-18 (“[Q.] The fact that you used adenosine on your own skin and observed that there was a decrease in elasticity and a diminution of fine lines and wrinkles, would that

have satisfied the patent claims in the '327 and '513 patent? . . . THE WITNESS: Assuming so, yes. [Q.] Okay. And the point being is that a subject[ive] assessment of a diminution of fine lines and wrinkles or decrease in elasticity does satisfy or qualify as enhancing the condition of the skin, as you've defined it in the patent; correct? . . . THE WITNESS: Yes."); *see also id.* at 33:9-19, 34:8-18, 35:9-21, 36:4-7, 37:17-38:5, 167:7-11 & Ex. 18 at 9-10; SOF, ¶ 10.) Indeed, even when assessments are guided by specific parameters or grading scales (which is not the case in the patents-in-suit), they can and do produce conflicting results, which Dr. Michniak-Kohn has not disputed. (SOF, ¶ 11.)

In sum, the “enhance the condition of the skin” claim language is so pliable that it can be argued to be infringed or not depending on whether, for example, a “second party” believes there is a reduction or not. That kind of vagueness of claim scope violates the requirements of clear public notice, and such terms have been repeatedly held invalid for indefiniteness following *Nautilus*. *See, e.g., Intellectual Ventures I LLC v. T-Mobile USA, Inc.*, 902 F.3d 1372, 1381 (Fed. Cir. 2018) (“[A] term of degree [*i.e.*, “optimiz[ing] TTT QoS”] that is ‘purely subjective’ and depends ‘on the unpredictable vagaries of any one person’s opinion’ is indefinite.”); *Interval Licensing*, 766 F.3d at 1371 (“The patents’ ‘unobtrusive manner’ phrase is highly subjective and, on its face, provides little guidance to one of skill in the art.”); *see also HIP, Inc. v. Hormel Foods Corp.*, No.

18-615-CFC, 2019 WL 2579266, at *2 (D. Del. June 24, 2019) (granting summary judgment that “resembling a pan-fried bacon product” is indefinite where “[t]he claims do not define or otherwise clarify the scope of the disputed term” and the specification provided multiple ways to make such a determination), *aff’d*, 796 F. App’x 748 (Fed. Cir. 2020); *accord Datamize*, 417 F.3d at 1352-53 (“Simply put, the definition of ‘aesthetically pleasing’ cannot depend on an undefined standard. [Nor can it] depend on the undefined views of unnamed persons, even if they are experts, specialists, or academics.”).

The incorporation of purely subjective methodologies for assessing skin enhancement is a sufficient and independent basis for finding indefiniteness. But the patents-in-suit are also indefinite because the multiple available methodologies, including those described in the patent as objective, can and do produce conflicting results depending on the studied parameter, thereby increasing the uncertainty and ambiguity. (*See* Ex. 5, ¶ 261 (“As explained by Dobos 2015, ‘[m]ore than 100 skin ageing scales exist, which makes it difficult to choose outcomes measures and to compare study results.’ Moreover, ‘[e]vidence supporting the validity and reliability of the majority of scales is poor’, and ‘there is no evidence of which scales perform best, making the selection of appropriate tools for clinical practice and research challenging.’”); *see also id.* at ¶ 262; SOF, ¶ 12.) Dr. Dobson’s testimony confirms this very point:

[Q] Okay. Focusing on, for example, wrinkling, there's more than one test that can be used to determine whether or not you're improving wrinkling; correct?

A. I would -- yes.

Q. And depending on the tests that you use, a formulation can show an improvement in wrinkling in one test but no improvement in wrinkling in the other test for that same formulation; correct? . . .

THE WITNESS: That's a possibility.

Q. (BY MR. ASHKENAZI) Yes. And the same thing would be true for roughness; correct? . . .

THE WITNESS. I assume so.

(Ex. 17 at 171:1-15.) Once again, Dr. Michniak-Kohn has not disputed the opinions of Dr. Gerald Kasting, L'Oréal USA's expert, in this regard. (SOF, ¶ 11; Ex. 12, ¶¶ 184-88.)

Instead, Dr. Michniak-Kohn opines that “the asserted patents provide flexibility for the skilled artisan to select the desired assessment standard” and that a person of ordinary skill in the art (“POSA”) “may use different assessment criteria.” (Ex. 12, ¶¶ 187-88.) But “flexibility” to create infringement assertions and the ability to use *various “criteria”* does *not* help a POSA understand, with reasonable clarity from the patent, *which criteria to use* to determine whether a given product is within the scope of the claims. (SOF, ¶ 14.) 35 U.S.C. § 112 ¶ (2) requires “reasonable certainty,” and, where there are multiple assessments that produce different results and the specification does not provide guidance between them, the claims are invalid. *See HZNP Med.*, 940 F.3d at 698 (finding

indefiniteness where claimed parameter could be assessed using two tests that “do not provide consistent results”); *Butamax*TM, 117 F. Supp. 3d at 641-42 (similar).

B. Plaintiffs Cannot Now Ignore Their Claim Language to Avoid Indefiniteness

During expert discovery, Plaintiffs asserted that the need for the amount of adenosine to “enhance the condition of the skin” is not a claim limitation because the phrase “enhancing the condition of unbroken skin” appears in the claim preamble. (Ex. 11, ¶¶ 65, 68-69.) That is wrong. The language “an amount effective *to enhance the condition of the skin*” is in the *body* of the claim. (Ex. 1, 10:23-24.) It cannot be ignored. *See Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997) (“‘Comprising’ is a term of art used in claim language which means that the named elements are essential”); *HZNP Med.*, 940 F.3d at 692 (“[C]laim language should not be treated as meaningless.”).

Moreover, in this case, the preamble language is an essential part of the claim in that it defines how the “enhanc[ement],” already appearing in the claim body, occurs: “by reducing one or more of wrinkling, roughness, dryness, or laxity of the skin.” (Ex. 1, 10:17-20, 10:23-24.)

Plaintiffs expressly relied on this language when they argued to the Patent & Trademark Office (“PTO”) that the patents-in-suit should be granted. In response to a PTO rejection, the applicants added the “reducing one or more of wrinkling, roughness, dryness, or laxity of the skin, without increasing dermal cell

proliferation” claim language. (*See* Ex. 24 at CARMEL LABS_00000791; SOF, ¶ 15-16.) In doing so, they pointed to the patent specification, where it states that skin is enhanced “when there is a noticeable decrease in noticeable decrease [*sic*] in the amount of wrinkling, roughness, dryness, laxity, sallowness, or pigmentary mottling of the treated skin,” and explained they were amending the claim to recite “a method for enhancing the condition of unbroken skin of a mammal by reducing one or more of wrinkling, roughness, dryness, or laxity of the skin” (thereby removing “sallowness, or pigmentary mottling”). (*Id.* at CARMEL LABS_00000793; SOF, ¶ 16.)⁴ Accordingly, even if the disputed language were only in the claim preamble—which it is not—the language would still be a limitation. *See, e.g., In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1347 (Fed. Cir. 2002) (preamble language is limiting when it “recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim” or was

⁴ Moreover, the applicants relied on the preamble language to attempt to distinguish prior art during prosecution. *See, e.g., id.* at CARMEL LABS_00000796 (“Applicants apply adenosine as a cosmetic approach to enhance the condition or complexion of the skin, whereas Cronstein describes a medical therapy for open wounds such as burns.”).

relied on “during prosecution to distinguish the claimed invention from the prior art”); *Griffin v. Bertina*, 285 F.3d 1029, 1033-34 (Fed. Cir. 2002) (similar).

Finally, during fact discovery, Plaintiffs argued that this language was limiting. (*See* SOF, ¶¶ 18-19.) And, when addressing indefiniteness during fact discovery, Plaintiffs did not assert that this language was not limiting. (*See* SOF, ¶ 19.) The parties therefore proceeded based on this understanding. Plaintiffs cannot and should not be permitted to argue in response to this summary judgment motion that express claim terms may be simply ignored, including for purposes of indefiniteness. And if language appearing in the patent claim and the specification, and relied upon during patent prosecution, could be simply ignored by a patentee later at the time of trial of a claim of infringement, such a claim would be a poster child for indefiniteness.

VI. CONCLUSION

For the reasons set forth above, L’Oréal USA respectfully requests that the Court grant summary judgment of indefiniteness of the patents-in-suit.

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CERTIFICATE OF SERVICE

I hereby certify that on September 11, 2020, a true and correct copy of the foregoing document was filed with the Clerk of Court via CM/ECF which will send notification of such filing to counsel of record and I further certify that a true and correct copy of the foregoing document was caused to be served on the following counsel of record as indicated:

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